

REMARKS

Applicant has made amendments to the claims pursuant to the Examiner's rejections and requests reconsideration of the application of the present invention. Applicant believes that the double patenting rejection of Claims 12 and 13 has been removed, in light of the amendments made to Claims 4 and 5 to reflect a change in dependency.

**I. Rejection of Claims 1-13 under 35 USC 103(a) as being unpatentable over Takaichi et al. in view of Wilen, Needleman et al, Theeuwes, and Buysch et al.**

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as unpatentable over Takaichi et al. in view of Wilen, Needleman et al, Theeuwes, and Buysch et al.

According to the Examiner, the Takaichi et al. reference discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the compositions. Furthermore, the amount of calcium oxide to be included in the composition is not to exceed 1.0% by weight. As suggested by the Examiner, the Takaichi reference does not teach a composition comprising magnesium sulfate, as a sole anhydrous compound, or in combination with calcium oxide. Furthermore, the Takaichi reference does not even suggest or provide motivation to combine calcium oxide with magnesium sulfate. The purpose of the calcium oxide within the Takaichi reference is to serve as a moisture absorption medium.

In contrast, the present invention discloses and teaches the combined use of calcium oxide and a magnesium salt to provide not only a desiccating effect but also a nutritional supplement. The Takaichi reference makes no suggestion that magnesium salts should be used

in combination with the calcium oxide. In addition, the present invention discloses a range of calcium oxide that is up to 10% by weight of the composition, and preferably from about 4-8% by weight of the composition. On the other hand, the Takaichi reference teaches that the amount of calcium oxide to be included in the composition is not to exceed 1.0% by weight of the composition. The Takaichi reference suggests that calcium oxide can not exceed levels greater than 1% by weight of the composition, whereas, the preferred range of calcium oxide in the present invention is above 1%, more preferably 4-8% by weight of the composition. It is asserted by the Applicant that the Takaichi reference fails to meet the preferred calcium oxide element as relied upon by the Examiner. The Examiner asserts that in light of the Takaichi reference it would have been obvious to use up to 10% calcium oxide, and more particularly 4-8% calcium oxide, in a combination. Applicant respectfully disagrees, and suggests that the Takaichi reference fails to suggest a motivation to using calcium oxide in the amounts provided by the present invention. The Takaichi reference discloses combinations of calcium oxide and silicon dioxide in predetermined amounts, more specifically the reference teaches against adding large amounts of calcium oxide (pg. 4, lines 13-19) and identifies problems associated therewith. In light of the above remarks, the Takaichi reference does not establish a basis for the rejection as provided by the Examiner.

According to the Examiner, the Wilen reference, US Patent No. 2,297,599, teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (as seen in Example 2). The Examiner suggests that it would have been obvious to one skilled in the art to present magnesium sulfate in a quantity less than 10% by weight of the composition.

Applicant suggests that although the Wilen references teaches a composition that comprises magnesium sulphate, it fails to teach or suggest the benefits of a mixture of calcium oxide and anhydrous or calcined magnesium sulphate. The Wilen reference (issued 1940) does not provide any motivation to prepare a combination of magnesium sulphate with a predetermined amount of calcium oxide. The Wilen reference is concerned with effervescent tablets. In particular, Example 2, provides a tablet containing magnesium sulphate and calcium gluconate. The calcium gluconate does not provide the desiccating effect as provided by the calcium oxide of the present invention. More particularly, it would not have been obvious to substitute the calcium oxide component of the present invention in place of the calcium gluconate as provided in the Wilen reference.

In contrast, the calcium oxide and magnesium sulfate combination of the present invention was specifically selected to provide not only a desiccating effect but also a nutritional supplement that works in combination to counter the individual effects that each salt can have on the intestinal track alone. Therefore, the combination of the magnesium sulfate and calcium oxide is key to the desired performance of the present invention. The Wilen reference, while disclosing a composition containing calcium gluconate and magnesium sulphate for providing an effervescent tablet, provides no teaching as to why the specific components are used in combination and in the amounts indicated to provide the benefits of the present invention.

Applicant further suggests that the combination of calcium oxide and magnesium sulphate as provided in the present invention provides three main benefits. First, the present invention serves as a particularly good desiccating effect (as shown in table 1). In addition, the combination provides a balanced bowel effect, which is not present if either calcium oxide or magnesium sulphate are used alone. Finally, the preferred amounts of each of the components

have a remineralising effect. Although the Examiner suggests that the two components, calcium oxide and magnesium sulphate, are known in the art, it has been established that an invention is not obvious where "old" or "well known" elements solve different problems. The claimed invention must be considered as a whole. Applicant asserts that even though calcium oxide and magnesium sulphate have been used in various effervescent formulas individually, it is the combination of the components in the desired amount that provide the overall present invention and serve as a basis for patentability.

The Examiner further suggests that the Needleman, Theeuwes and Buysch references each teach various effervescent materials. In light of the above remarks related to the Takaichi and Wilen references, as well as the benefits provided by the present invention, Applicant asserts that the rejections based on these references are rendered moot. Applicant believes that none of the cited references suggest or teach the benefits and effects as established above for the present invention. This is especially true since the Takaichi reference teaches not to use calcium oxide in such high amounts, as suggested by the present invention. Therefore, one of ordinary skill in the art would not have been motivated to combine the teachings of the cited references, and in particular with respect to the desired combinations.

In light of the amendments provided and the above remarks, Applicant believes that the Examiner's rejections have been removed and respectfully request reconsideration of the rejection.

**II. Rejection of Claims 14-16 under 35 USC 103(a) as being unpatentable over Takaichi et al. in view of Wilen, Needleman et al, Theeuwes, and Buysch et al.**

In light of the above remarks regarding the Takaichi reference and the Wilen reference, Applicant believes the Examiner's rejections have been removed. Neither the Wilen, Needleman, Theeuwes or Buysch references either alone or in combination with the Takaichi reference disclose or would suggest to one skilled in the art the combination of calcium oxide and magnesium sulfate as provided in the amended claims of the present invention.

As disclosed on the bottom of page 2 to the top of page 3 of the specification of the present invention, the calcium oxide and magnesium sulfate are selected to counter each other in terms of their constipating and diarrhoeal effects. Furthermore, as provided on page 15 of the specification, the combined minerals can provide the end product with re-mineralizing concentrations of calcium and magnesium. The provided combinations of the present invention, as well as the desired effects, would not have been obvious based on the suggested references. Therefore, in light of the provided references, the combination of the calcium oxide and magnesium sulfate of the present invention would not have been obvious.

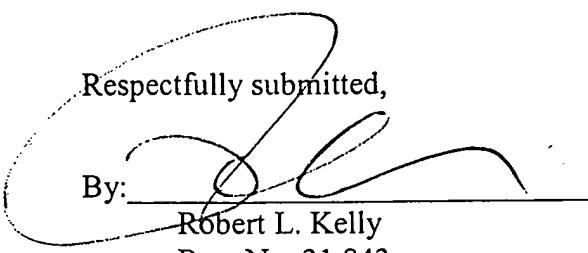
Applicant respectfully requests reconsideration by the Examiner.

### **III. CONCLUSION**

In view of the foregoing amendments and submissions, Applicant respectfully requests that the rejection of pending claims 1 and 4 - 16 be withdrawn. Applicant requests consideration of the amended claims and requests allowance in light of the provided remarks. If the Examiner should have any questions, please contact the undersigned for any further clarification. Applicant hereby requests further consideration of the application.

Date May 27, 2003

Respectfully submitted,

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### **CERTIFICATE OF EXPRESS MAILING**

I hereby certify that the enclosed Response is being deposited with the United States Postal Service as Express Mail No. ET843550979US, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 27th day of May, 2003.

  
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Patricia A. Kniola